IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

JAN VALLEJO, *INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF STEVE VALLEJO,*

Plaintiff,

v.

AMGEN INC. *ET AL.*,

Defendants.

Case No.: 8:14-cv-00050-LSC-CRZ

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT AMGEN INC.'S MOTION TO DISMISS THE COMPLAINT

Pursuant to Federal Rule of Civil Procedure 12(b)(6), Defendant Amgen Inc. ("Defendant" or "Amgen"), respectfully submits this Memorandum of Law in support of its motion to dismiss the Complaint filed by Plaintiff Jan Vallejo.

I. INTRODUCTION

In this wrongful death products liability action, Plaintiff, as personal representative of the Estate of Steve Vallejo, alleges that Mr. Vallejo died as a result of his use of Enbrel®, a biological product approved for the treatment of serious autoimmune disease. Plaintiff contends that Defendant failed to adequately warn Mr. Vallejo of the risk that a patient taking Enbrel® might develop myelodysplastic syndrome, a hematological disorder associated with ineffective production of certain blood cells. Plaintiff's Complaint also alleges that Defendant failed to warn Mr. Vallejo of the risk of serious infection associated with the use of Enbrel®.

One problem with Plaintiff's theory, however, is that the package insert for Enbrel® warned Mr. Vallejo's health care providers of the risks of both hematologic events and serious infections. Plaintiff's claims therefore are barred by the "Learned Intermediary Doctrine," a legal doctrine that precludes claims against a drug manufacturer when adequate warnings

regarding the risks associated with a drug have been provided to a plaintiff's prescribing physician.

Further, even if the Learned Intermediary Doctrine had no application to this case, Plaintiff's Complaint would be subject to dismissal. As explained below, Plaintiff's individual claims suffer from a long list of legal deficiencies:

- Plaintiff cannot pursue claims based upon a failure to report adverse events to the FDA because all such claims are preempted;
- Nebraska law does not recognize a claim based upon a post-sale duty-to-warn;
- Plaintiff's fraud claim is barred by judicial estoppel because she voluntarily agreed in an earlier proceeding not to pursue that claim in this Court;
- Plaintiff's fraud claim also fails because the Nebraska Uniform Deceptive Trade Practices Act does not provide a private right action to recover monetary damages and because Plaintiff has not satisfied the pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure;
- Plaintiff's claim for defective design fails because the Complaint does not allege facts that satisfy Nebraska's consumer expectations test;
- Plaintiff's claim for breach of express warranty fails because Plaintiff has not identified any particular warranty by Defendant;
- Plaintiff's wholly conclusory claim of negligence fails to satisfy federal pleading requirements; and
- Plaintiff's claim for loss of consortium is derivative of Plaintiff's other defective claims and therefore fails.

Unfortunately, each of these legal defects requires separate consideration below. Ultimately, however, all the defects in Plaintiff's Complaint derive from the same shortcoming: Defendant cannot be held liable simply because a risk it fully disclosed allegedly led to the alleged injuries. Plaintiff's Complaint thus fails as a matter of Nebraska law and should be dismissed.

II. STATEMENT OF FACTS

A. Mr. Vallejo is Prescribed Enbrel®

Plaintiff brings this action on her own behalf and as representative of her deceased husband, who allegedly used Enbrel®, a biological medication available only by prescription. (Comp. ¶¶ 1-2). Enbrel® was first approved by the United States Food and Drug Administration ("FDA") in November 1998 for the treatment of rheumatoid arthritis. 1 Since its approval, the FDA has approved expanded uses of Enbrel® for various other indications, including but not limited to plaque psoriasis and psoriatic arthritis.

The Complaint does not allege the purpose for which Mr. Vallejo used Enbrel®. In fact, the only relevant facts alleged in the Complaint regarding Mr. Vallejo are: (1) that he began using Enbrel® in "approximately 2004" for an unspecified purpose (Comp. ¶ 22); (2) that he developed myelodysplastic syndrome as a result of his use of Enbrel® (*Id.* at ¶ 23); (3) that he allegedly received inadequate warnings regarding the risks of infection and myelodysplastic syndrome (*Id.* at ¶¶ 20-23); and (4) that he passed away on May 21, 2011, allegedly as a result of complications arising from his use of Enbrel® (*Id.* at ¶ 24).

B. Mr. Vallejo's Condition and the Warnings provided by Defendant

Plaintiff's entire Complaint ultimately rests upon the allegation that Defendant failed to warn of the risks associated with the use of Enbrel®. In fact, however, the package insert

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1 Enbrel®, also known as Etanercept, is an injectable biologic product that replicates a type of protein made by the body's immune system called a tumor necrosis factor ("TNF") blocker. Enbrel® inhibits TNF, which is a chemical messenger that helps regulate the inflammatory process. *See* FDA, *Etanercept Product Approval Information - Licensing Action 12/2/98***,** http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm080536.htm; *see also* Comp. ¶¶ 16, 19. In considering Defendant's Rule 12(b)(6) motion to dismiss, this Court may consider information found on the FDA's website. *See, e.g., In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, MDL No. 08-1905, 2009 WL 294353, at *3, n.2 (D. Minn. Feb. 5, 2009), *aff'd* 623 F.3d 1200 (8th Cir. 2010).

accompanying Plaintiff's medication explained these risks in detail. In particular, that package insert addressed the two risks identified in Plaintiff's Complaint: (1) the risk of severe infection; and (2) the risk of developing a hematological disorder.

With respect to the risk of serious infection, Plaintiff alleges that "Defendants downplayed the risk of side effects including the real and dangerous risk of developing complications arising from serious and significant infection." (Comp. ¶ 20). She also alleges that Mr. Vallejo was entitled to disclosure of "his relative risk of developing complications from serious and significant infection." (*Id.* at ¶ 21).

In reality, the Enbrel® package insert 2 in effect at the time Mr. Vallejo first was prescribed Enbrel® discusses in detail the precise risk of infection alleged in Plaintiff's Complaint. For example, in the "Warnings" section of the insert, set forth in bold and all-capital lettering, is the following information regarding the risk of infection:

INFECTIONS

> **IN POST-MARKETING REPORTS, SERIOUS INFECTIONS AND SEPSIS, INCLUDING FATALITIES, HAVE BEEN REPORTED WITH THE USE OF ENBREL®. . . . PATIENTS WHO DEVELOP A NEW INFECTION WHILE UNDERGOING TREATMENT WITH ENBREL® SHOULD BE MONITORED CLOSELY. ADMINISTRATION OF ENBREL® SHOULD BE DISCONTINUED IF A PATIENT DEVELOPS A SERIOUS**

2 The Court may take judicial notice of relevant documents and materials, in accordance with Rule 201 of the Federal Rules of Evidence, without converting the instant Motion into a motion for summary judgment. *See Levy v. Ohl*, 477 F.3d 988, 991 (8th Cir. 2007); *see also Papasan v. Allain*, 478 U.S. 265, 268 n.1 (1986). "[I]n considering a motion to dismiss, the district court may sometimes consider materials outside the pleadings, such as materials that are necessarily embraced by the pleadings and exhibits attached to the complaint." *Mattes v. ABC Plastics Inc.*, 323 F.3d 695, 697 n.4 (8th Cir. 2003). Courts also "may take judicial notice of judicial opinions and public records." *Stutzka v. McCarville*, 420 F.3d 757, 760 n.2 (8th Cir. 2005). Rule 201 requires that the Court *must* take notice of such documents "if a party requests it and the court is supplied with the necessary information." Fed. R. Evid. 201(c)(2).

> **INFECTION OR SEPSIS. TREATMENT WITH ENBREL® SHOULD NOT BE INITIATED IN PATIENTS WITH ACUTE INFECTIONS, INCLUDING CHRONIC OR LOCALIZED INFECTIONS.**

(*See* Ex. A hereto at pg. 14). Similarly, the "Adverse Reactions" section of the package insert describes the risk of infection in detail and expressly notes that "[i]nfections have been noted in all organ systems and have been reported in patients receiving ENBREL® alone or in combination with immunosuppressive agents." (*Id.* at pg. 19).

A similar disconnect exists between Plaintiff's allegations regarding the Decedent's hematological disorder and the contents of the Enbrel® package insert. Plaintiff alleges that Defendant provided inadequate warnings regarding myelodysplastic syndrome. (Comp. ¶¶ 25-26). This syndrome refers to a hematological disorder in which the bone marrow does not produce enough healthy blood cells. 3 It is an umbrella term that covers both hematological malignancies (*i.e.*, "cancers") and other hematological disorders 4 – although the Complaint does not specify the exact nature of the condition experienced by Mr. Vallejo. Those who suffer myelodysplastic syndrome face an increased risk of severe infection. 5

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3 *See* National Cancer Institute, *General Information about Myelodysplastic Syndromes,* http://www.cancer.gov/cancertopics/pdq/treatment/myelodysplastic/patient (hereafter, "Cancer.gov Website"). The Court may take judicial notice of information found on government websites. *See, e.g., Gent v. CUNA Mut. Insur. Soc.*, 611 F.3d 79, 84 n. 5 (1st Cir. 2010) (taking judicial notice of background information regarding Lyme disease found on Center for Disease Control website).

4 *Compare* Cancer.gov Website (describing it as a type of cancer) *with* Bachegowda, et al., "Signal Transduction Inhibitors in Treatment of Myelodysplastic Syndromes," Journal of Hematology & Oncology (2013) (describing it as "a group of hematologic disorders").

5 *See* Cancer.gov Website. It is not clear from the Complaint whether Plaintiff claims that her husband developed severe infection as a result of myelodysplastic syndrome. *See* Comp. ¶¶ 20-21 (discussing warnings regarding the risk of infection). Plaintiff may have intended only to allege that her husband suffered myelodysplastic syndrome and included allegations regarding infections in her Complaint by error. For purposes of this motion to dismiss, however, Defendant necessarily treats the allegations of Plaintiff's Complaint as true.

The package insert in effect when Mr. Vallejo was prescribed Enbrel® contained a specific section on the potential risk of hematologic events and stated:

Hematological Events

> Rare reports of pancytopenia including aplastic anemia, some with a fatal outcome, have been reported in patients treated with ENBREL®. The causal relationship to ENBREL® therapy remains unclear. Although no high risk group has been identified, caution should be exercised in patients being treated with ENBREL® who have a previous history of significant hematologic abnormalities. All patients should be advised to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever, bruising, bleeding, pallor) while on ENBREL®. Discontinuation of ENBREL® therapy should be considered in patients with confirmed significant hematologic abnormalities.
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> Two percent of patients treated concurrently with ENBREL® and anakinra developed neutropenia (ANC < 1 x 10^9/ L). While neutropenic, one patient developed cellulitis which recovered with antibiotic therapy.

(Ex. A at 15).

And, immediately below that warning is a section on malignancies, which is a category into which some physicians classify myelodysplastic syndrome, 6 warning:

Malignancies

> In the controlled portions of clinical trials of all the TNF-blocking agents, more cases of lymphoma have been observed among patients receiving the TNF blocker compared to control patients. During the controlled portions of ENBREL® trials, 1 lymphoma was observed among 2502 ENBREL®-treated patients versus 0 among 921 control patients (mean duration of controlled treatment approximately 6 months). In the controlled and open-label portions of clinical trials of Enbrel® in rheumatoid arthritis patients, 6 lymphomas were observed in 3389 patients over approximately 8000 patient-years of therapy. This is 2-fold higher than that expected in the general population. While patients with rheumatoid arthritis, particularly those with highly active disease, may be at a higher risk (up to several fold) for the development of

6 *See* Cancer.gov website (labeling myelodysplastic syndrome a "type of cancer").

> lymphoma, the potential role of TNF-blocking therapy in the development of malignancies is not known.

(*Id.* at pg. 15). Similarly, the "Adverse Reactions" section notes that clinical trials indicated an increased incidence of lymphoma, a hematological cancer, for those taking Enbrel®. (*Id.* at pg. 20). Hematologic events are also described in the "Adverse Reaction Information from Spontaneous Reports." (*Id.* at pg. 24).

Given these plain warnings, Mr. Vallejo's medical providers had full notice of the potential risks associated with the use of Enbrel®. They had been expressly warned of the potential risk of complications arising from serious infection. They also had been warned that those using Enbrel® may experience an increased risk of hematological events and malignancies, such as lymphoma.

III. ARGUMENT

A. The Governing Standards

In evaluating the legal sufficiency of Plaintiff's Complaint, this Court must apply the strict pleading requirements set forth by the United States Supreme Court in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). *See also Houston v. Mylan, Inc.*, 2009 WL 8563604, at *1 (D. Neb. Nov. 20, 2009). As these cases make clear, "[the] complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. This requires allegations showing more than a mere possibility that a defendant has acted unlawfully. *Id.* at 679. "[A]n unadorned, the defendant-unlawfully-harmed-me accusation" is insufficient. *Id.* at 678.

"Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the court to draw on its judicial experience and common sense." *Houston*, 2009 WL 8563604, at *1 (citation omitted). Upon applying its judicial experience and common sense to this case, the Court should dismiss Plaintiff's Complaint.

B. Plaintiff Fails to State a Claim for Strict Liability or Negligent Failure to Warn.

1. Plaintiff's Strict Liability and Negligent Failure to Warn Claims are barred by the Learned Intermediary Doctrine.

As the Nebraska Supreme Court has explained "[p]harmaceutical products have historically been treated differently" than other products. *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 841 (Neb. 2000). With respect to such products, courts now apply the Learned Intermediary Doctrine to dismiss claims against prescription drug manufacturers. This principal of law is:

> [B]ased upon the premise that, as a medical expert, a patient's treating physician is in the best position to evaluate the often complex information provided by the manufacturer concerning the risks and benefits of its drug or product and to make an individualized medial judgment, based on the patient's particular needs and susceptibilities, as to whether the patient should use the product.

Id. (citation omitted)*; see also Tyler v. Bristol-Meyer Squibb*, 2010 WL 1664967, at *1-2 (D. Neb. Apr. 23, 2010) (discussing learned intermediary doctrine under Nebraska law).

Under the Learned Intermediary Doctrine, "prescription drug manufacturers can satisfy their duty to warn by warning prescribing physicians of the risks associated with a drug, rather than warning patients directly." *In re Levaquin Prods. Liab. Litig.*, 700 F.3d 1161, 1166 (8th Cir. 2012) (describing learned intermediary doctrine as applied in Minnesota); *see also West v. Searle & Co.*, 806 S.W.2d 608, 613 (Ark. 1991) (explaining Learned Intermediary Doctrine "provides that a drug manufacturer may rely on the prescribing physician to warn the ultimate

consumer of the risks of a prescription drug"). And as decisions in other jurisdictions have recognized, a court applying the Learned Intermediary Doctrine may rule as a matter of law on the adequacy of warnings provided to a plaintiff's physician. *See, e.g., Felix v. Hoffman-La Roche, Inc.*, 540 So.2d 102, 105 (Fla. 1989) (collecting cases).

Here, the Plaintiff should not avoid dismissal simply by alleging that Defendant's warnings regarding infection or hematological cancer were inadequate because the warnings failed to include some specific word, phrase, description or medical term that is specific to this patient. That, actually, is exactly what the Learned Intermediary Doctrine seeks to avoid. Stated differently, the package insert that accompanied Enbrel® when it was prescribed to Mr. Vallejo clearly warned of the risks associated with infection and hematological events. And the Plaintiff just cannot escape that fact. *See Mills v. Bristol-Myers Squibb Co.*, 2011 WL 3566131, at *3 (D. Ariz. Aug. 12, 2011) (dismissing a failure to warn claim because plaintiff did not "plead any facts about what the [drug] label said or how it was deficient" and "the warning did describe a risk of [the alleged injury]"); *Wendell v. Johnson & Johnson*, 2010 WL 271423, at *4 (N.D. Cal. Jan. 20, 2010) (dismissing a failure to warn claim because the plaintiffs "fail[ed] to allege how [the] warnings about [the drug] were inadequate").

In sum, through the package insert accompanying Enbrel®, Defendant fully discharged its duty to warn of the potential risks facing patients who inject Enbrel®. This dooms Plaintiff's claims for strict liability failure to warn and wrongful death.

2. Plaintiff's Strict Liability and Negligent Failure to Warn Claims are Impliedly Preempted by Federal Law.

In the strict liability failure to warn (Count II) and negligence (Count IV) counts of the Complaint, Plaintiff repeatedly alleges that Defendant violated federal disclosure and reporting

requirements by failing to provide adequate information to the FDA regarding Enbrel®. *See, e.g.*, Comp. ¶¶ 48, 50, 73, 80, 81, 84, 86. Any such claims, however, are impliedly preempted.

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the United States Supreme Court held that the FDCA preempts state law claims alleging fraud on the FDA because such claims critically rely on federal law and there is no federal private cause of action for violations of the FDCA. *See id.* at 348-53; *see also PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2578 (2011) (citing *Buckman* for this proposition); *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (explaining that under the *Buckman* implied preemption doctrine, "the plaintiff must not be suing *because* the conduct violates the FDCA" (citation omitted)); *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1119 (9th Cir. 2013) (holding that claims resting "solely on the non-disclosure to patients of facts tied to the scope of [FDA premarket approval]" are impliedly preempted because they conflict with the "FDCA's enforcement scheme").

Like the Plaintiff in *Buckman*, the Plaintiff here seeks to usurp the role of the FDA and enforce federal regulations governing FDA reporting requirements. As the United States Supreme Court has made clear, all claims based upon such a theory are preempted and should be dismissed. 7

3. Plaintiff's Strict Liability and Negligence Claims are Barred to the Extent They Allege a Post-Sale Duty to Warn

The Complaint alleges that Defendant had an ongoing duty of pharmacovigilance that it allegedly breached by failing to adequately warn of the risks associated with Enbrel®. *See, e.g.*, Comp. ¶¶ 48, 78, 79. But because Plaintiff's allegations are conclusory and fail to specify how

7 In addition, FDA reporting/disclosure regulations are administrative requirements that do not define a standard of care and therefore may not form the basis of a negligence per se claim. *See Uribe v. Sofamor, S.N.C.*, No. 8:95-cv-464, 1999 WL 1129703, at *16 (D. Neb. Aug. 16, 1999).

or when this failure of pharmacovigilance occurred, it is not clear whether Plaintiff alleges that Defendant should have conducted activities leading to additional warnings *after* they sold the Enbrel® products that Plaintiff's decedent purchased and used.

To the extent Plaintiff's claims depend on such post-sale allegations, they are barred under Nebraska law. Nebraska does not recognize a post-sale duty of product manufacturers. To the contrary, in *Anderson v. Nissan Motor Co., Ltd.*, 139 F.3d 599, 602 (8th Cir. 1998), the Court of Appeals for the Eighth Circuit held that Nebraska law would limit the reach of products liability law to actions or omissions which occur at the time of manufacture or sale. Thus, under Nebraska law, Defendant had no post-sale duty to warn regarding the risks associated with Enbrel®. 8

C. Plaintiff's Fraud Claim Fails as a Matter of Law

Plaintiff has included in her Complaint a claim for "fraud" that alleges unspecified violations of the "Nebraska Unfair Trade Practices Act" [sic]. *See* Comp. ¶¶ 100-04. This claim is barred for three separate reasons. First, Plaintiff is judicially estopped from bringing such a claim because she previously agreed to drop this allegation in a previously-filed lawsuit. Second, no private right of action exists under the Nebraska Deceptive Trade Practices Act for monetary damages. Third, Plaintiff has failed to plead "fraud" with the particularity required by Rule 9(b) of the Federal Rules of Civil Procedure.

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8 Similarly, Plaintiff cannot rely on federal regulations to assert a post-sale duty to warn theory under the guise of a negligence per se claim. Where no underlying duty or cause of action exists under state law, federal law cannot create out of whole cloth a state law negligence cause of action. *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1163 (D. Minn. 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010); *see also Orduna v. Total Constr. Servs., Inc.*, 713 N.W.2d 471, 479 (Neb. 2006) (holding that violation of a statute or regulation is not negligence as a matter of law but may constitute evidence supporting an existing state law negligence cause of action).

1. Plaintiff Fraud Claim is Barred by Judicial Estoppel.

Plaintiff first initiated this litigation by filing suit in the Superior Court of California, County of Ventura (the "California Superior Court'). Because the key facts and witnesses in this case center upon Nebraska, however, Defendants (Amgen and its co-defendants in this action) moved to dismiss the California action on grounds of *forum non conveniens*. On November 13, 2013, the California Superior Court issued a "tentative ruling" granting Defendants' motion to dismiss subject to certain conditions. (*See* Ex. B hereto). Subsequently, after consultations with the parties, the Court entered an agreed-upon order that imposed conditions on both parties. Defendants, for example, agreed not to assert defenses of lack of jurisdiction or statute of limitations. In exchange, Plaintiff agreed that any new action filed in this Court would assert "the same or fewer of the causes of action asserted in this Action against the same or fewer of the Defendants named in this Action . . . ." (*See* Ex. C hereto). In blatant violation of this agreement, Plaintiff's Complaint contains an entirely new claim for "fraud" under Rule 9(b) that was not raised in her California action.

Plaintiff's fraud claim is barred by the doctrine of judicial estoppel. As the Nebraska Supreme Court has explained, "when a party has unequivocally asserted a position in a proceeding and a court accepts that position, judicial estoppel can bar that party's inconsistent claim against the same or a different party in a later proceeding. "*TFF, Inc. v. Sanitary and Improvement Dist. No. 59*, 790 N.W.2d 427, 431 (Neb. 2010). Judicial estoppel does not depend upon harm or prejudice to a party, but instead "protects the integrity of the judicial process by preventing a party from taking a position inconsistent with one successfully and unequivocally asserted by the same party in a prior proceeding." *Id.*

Here, Plaintiff unequivocally took the position that, if the California Superior Court imposed the conditions upon Defendants included in its Order of Dismissal, then she would assert only the "same or fewer" causes of action in this proceeding. Plaintiff thus succeeded in obtaining what she desired—namely, the conditions imposed upon Defendants by the California court. To prevent Plaintiff from taking a position that is clearly inconsistent from what she previously agreed to, this Court should enforce the bargain Plaintiff struck and hold that she now is judicially estopped from pursuing her fraud claim.

2. Plaintiff Cannot Recover under the "Nebraska Unfair Trade Practices Act"

Plaintiff's claim for a violation of the Nebraska "Unfair Trade Practices Act" 9 (the "UDTPA"), Nev. Rev. Stat. §§ 87-302 *et seq*., styled as "Fraud," also is deficient because it is based on a theory of damages not cognizable under the statute. Plaintiff asserts that Defendant's alleged acts and omissions "constitute conduct in violation of the Nebraska Unfair Trade Practices Act," (Comp. ¶ 101), and that Plaintiff "suffered damages recoverable and/or compensable under the aforementioned statutes." (*Id.* at ¶ 102).

Under the Nebraska Uniform Deceptive Trade Practices Act, however, "[a] person likely to be damaged by a deceptive trade practice of another may bring an action for, and the court may grant, an injunction under the principles of equity against the person committing the deceptive trade practice." Nev. Rev. Stat. § 87-303(a). Thus, "by its own terms, § 87–303(a) only provides for equitable relief consistent with general principles of equity." *Sid Dillon Chevrolet-Oldsmobile-Pontiac, Inc. v. Sullivan*, 559 N.W.2d 740, 746 (Neb. 1997). "The UDTPA, specifically § 87–303, does not provide a private right of action for damages." *Reinbrecht v. Walgreen Co.*, 742 N.W.2d 243, 247 (Neb. Ct. App. 2007); *see also Al'Amin v.*

9 The Act is actually titled the Uniform Deceptive Trade Practices Act.

McDonalds Corp., No. 8:01-cv-385, 2001 WL 35838208, at *3 (D. Neb. Sept. 7, 2001) (dismissing claim under UDTPA because plaintiffs sought only money damages for their alleged personal injuries). Further, "[b]ecause the UDTPA provides injunctive relief for 'a person likely to be damaged,' it provides relief from future damage, not past damage. [The plaintiff] must present evidence to support an inference of future harm to him." *Reinbrecht*, 742 N.W.2d at 248.

Plaintiff's fraud claim seeks money damages associated with the death of her husband. 10 But no such claim for money damages is available under the UDTPA. Nor can Plaintiff pursue a claim under the UDTPA for past harm. Count VII of the Complaint therefore fails as a matter of law.

3. Plaintiff has not Pled Fraud with the Specificity Required by Rule 9(b).

Plaintiff's fraud claim also fails to satisfy federal pleading requirements. "To satisfy the particularity requirements of Rule 9(b), the complaint must plead such facts as the time, place, and content of the defendant's false representations, as well as details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." *United States ex. rel. Jochi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006). Or, "[p]ut another way, the complaint must identify the who, what, where, when, and how of the alleged fraud." *Id.* (internal quotation marks omitted). "[C]onclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient" to satisfy Rule 9(b). *Schaller Tel. Co. Golden Sky Sys., Inc.*, 298 F.3d 736, 746 (8th Cir. 2002). The complaint must be "specific enough to give defendants notice of the particular misconduct which is alleged to

10 In the separate "Prayer for Relief," Plaintiff seeks among other things, "[e]quitable, injunctive and declaratory relief, including enjoining the Defendant from further selling or distributing the drug." Comp. p. 21. The Complaint's inclusion of this language does not convert Plaintiff's statutory count into a claim for injunctive relief. Count VII is predicated purely on harm that Plaintiff allegedly "suffered" in the past, *id.* at ¶¶ 102, 103, and does not allege that injunctive relief is necessary to prevent likely future harm to this Plaintiff, as required by statute.

constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *United States ex. rel. Costner v. United States*, 317 F.3d 883, 889 (8th Cir. 2003) (citation omitted).

Plaintiff's Complaint does not come close to satisfying this standard. Instead, Plaintiff merely alleges that Defendant engaged in "unconscionable commercial practices, deception, fraud, false promise, misrepresentation and/or the knowing concealment suppression or omission of material facts." (Comp. ¶ 101). Nowhere does Plaintiff allege the "time, place and content" of any supposed representations. *St. Luke's Hosp.*, 441 F.3d at 556. Nor does she allege precisely what she believes Defendant should have disclosed. Plaintiff's vague and general allegations of fraud falls far short of the pleading requirements imposed by Rule 9(b) and provide no information upon which Defendant can prepare its defense. For this reason, Plaintiff's fraud claim should be dismissed.

D. Plaintiff Fails to State a Claim for Strict Liability Defective Design.

Plaintiff fails to state a claim for defective design because she does not allege any facts to support the conclusory allegation that Enbrel® was defective and deviated from consumer expectations. In Nebraska, to recover in strict liability for a design defect, a plaintiff must show:

> (1) the defendant placed the product on the market for use and knew, or in the exercise of reasonable care should have known, that the product would be used without inspection for defects; (2) the product was in a defective condition when it was placed on the market and left the defendant's possession; (3) the defect is the proximate or a proximately contributing cause of the plaintiff's injury sustained while the product was being used in a way and for the general purpose for which it was designed and intended; (4) the defect, if existent, rendered the product unreasonably dangerous and unsafe for its intended use; and (5) the plaintiff's damages were a direct and proximate result of the alleged defect.

Jay v. Moog Automotive, Inc., 652 N.W.2d 872, 880-81 (Neb. 2002). With respect to the fourth item, to demonstrate that a prescription drug's design is unreasonably dangerous, "the plaintiff is

required to plead the consumer expectations test, as he or she would be required to do in any products liability case." *Freeman*, 618 N.W.2d at 840.

Under the consumer expectations test, it is not sufficient for the plaintiff merely to plead that the product harmed her, as such an allegation says nothing about the factual characteristics of the product that take it outside the contemplation of an ordinary consumer. *See id.* at 843 (merging doctrines of implied warranty and strict liability and stating "a plaintiff cannot rely solely on the fact that an accident occurred as proof that the product was not merchantable"); *Jenkins v. Amchem Prods., Inc.*, 886 P.2d 869, 890 (Kan. 1994) ("There must be a specific claim concerning what aspect of the design was defective for a plaintiff to prevail on a strict liability design defect claim."); *In re Toyota Unintended Acceleration Marketing, Sales Practices Prods. Liab. Litig.*, 754 F. Supp. 2d 1208, 1220 (C.D. Cal. 2010) (holding that to adequately plead under the consumer expectations test, the plaintiff must describe *how* the product failed to meet the minimum expectations of an ordinary consumer of that product).

Plaintiff's defective design claim fails to allege *any* facts identifying consumer expectations regarding Enbrel®. Nor does Plaintiff allege how Enbrel® deviated from those expectations. And no facts of any kind are alleged identifying a particular defect in the "design" of Enbrel®. Plaintiff's claim for design defect should be dismissed.

E. Plaintiff Fails to State a Claim for Breach of Express Warranty.

Plaintiff's express warranty claim fails to adequately allege the supposed content of any warranty and fails to provide any facts explaining how Enbrel® deviated from any affirmation of fact or promise made by any Defendant. In Nebraska, an express warranty may be created by "any affirmation of fact or promise made by the seller to the buyer which relates to the goods and

becomes part of the basis of the bargain." Neb. Rev. Stat. U.C.C. § 2-313(1)(a). 11 The seller "must have made a particularized representation," *Murphy v. Spelts-Schultz Lumber Co. of Grand Island*, 481 N.W.2d 422, 431 (Neb. 1992), and the plaintiff must have relied on the affirmation. *Mennonite Deaconess Home & Hosp., Inc. v. Gates Eng'g Co., Inc.*, 363 N.W.2d 155, 161-62 (Neb. 1985). "In order for an express warranty to exist, there must be something positive and unequivocal concerning the thing sold," or in other words, "an absolute assertion concerning the thing sold." *Brown v. Globe Labs., Inc.*, 84 N.W.2d 151, 161 (Neb. 1957) (citation omitted). A statement expressing an "opinion, belief, judgment, or estimate do[es] not constitute a warranty." *Id.*

Representations by drug manufacturers about drugs are typically qualified by explanations of possible risks and benefits and do not provide absolute guarantees of results for any given patient. An express warranty or "affirmation of fact" is not created by such an uncertain estimate of possibilities. *See Fraser v. Wyeth, Inc.*, 857 F. Supp. 2d 244, 257-58 (D. Conn. 2012) (applying Connecticut statute identical to the U.C.C. provision) ("[A] drug manufacturer's representation in advertising or a warning label that a product is safe or effective, or an advertisement or warning label that does not adequately highlight a particular known or knowable risk does not create an express warranty in the absence of a guarantee that the particular product is free from all harmful side effects."); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 818 (N.D. Ohio) (applying Ohio statute identical to the U.C.C. provision) ("[A]sserting that a product is 'safe and effective' is not sufficiently clear to create an express warranty."). *Goga v. Ortho Diagnostics, Inc.*, 456 N.Y.S.2d 476, 477 (N.Y. App. Div. 1982) (holding express warranty was not created by statement that drug "provides virtually complete

11 Neb. Rev. Stat. U.C.C. § 2-313(1)(a) is identical to Unified Commercial Code § 2-313(1)(a).

protection" from a disease since the phrase is not a guarantee of "100%, absolute" protection for the consumer).

Plaintiff's conclusory allegation of an express warranty here is contradicted by the documents referenced in the Complaint and is insufficient as a matter of law. Plaintiff alleges that Defendant warranted Enbrel® "was of merchantable quality, fit, safe and otherwise not injurious to the health and well-being of Decedent Steve Vallejo and capable of providing the appropriate therapy to Decedent Steve Vallejo." (Comp. ¶ 59). In fact, far from making unequivocal guarantees or absolute assertions that no one would be injured by the drug or that the drug was free from risk, Defendant's representations about Enbrel® in the package insert consistently warned of the possibilities of serious adverse events.

Moreover, Plaintiff's Complaint alleges no facts indicating how the performance of Enbrel® deviates from any affirmation of fact or promise. Plaintiff alleges that the drug is "unsafe, unmerchantable and unfit for its intended use." (Comp. ¶ 61). But terms like "unsafe" and "unmerchantable" are wholly conclusory and provide no factual basis for determining whether the drug fails to comply with any specific affirmation of fact. Plaintiff also fails to allege a single fact to support the conclusion that Enbrel® "does not provide the represented or intended therapy," (*id.*) as the Complaint does not even once assert that Enbrel® did not positively treat Decedent's unspecified condition.

In sum, Plaintiff's imprecise express warranty allegations amount to a claim that Defendant made some unspecified representations about the safety of the drug. Such conclusory and imprecise allegations fall well short of stating a claim for express warranty under Nebraska law.

F. Plaintiff Fails to Otherwise State a Claim for Negligence.

To the extent that Plaintiff purports to have any basis for her negligence claims (Count IV) other than allegedly inadequate warnings, she alleges no facts to support these claims. To establish negligence in a products liability case, the plaintiff must plead the elements of duty, breach, causation, and damages. *Jay*, 652 N.W.2d at 880.

Plaintiff alleges in a conclusory fashion that "Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control . . . of Enbrel®." (Comp. ¶ 67; *see also* Comp. ¶¶ 69 (alleging that Defendant continued to manufacture Enbrel® even it "knew, or should have known," that it posed a "serious risk of bodily harm"), 85 (boilerplate allegations that Defendant was negligent in "one or more" respects, including failing to adequately test, design, develop, and manufacture their products)).

But Plaintiff alleges no facts suggesting how the conduct of Defendant constituted a breach of duty and no facts to indicate what Defendant "knew, or should have known" at any given time. For example, the Complaint does not explain how Enbrel® could have been designed more safely or how the particular Enbrel® the decedent used was manufactured incorrectly. Instead, Plaintiff merely repeats general, conclusory allegations about Enbrel®. Plaintiff's bare conclusory allegations are insufficient under *Iqbal* and *Twombly* to state a claim for negligence.

Additionally, Plaintiff's claims fail because she does not allege how each defendant breached its duty. Instead, the Complaint impermissibly lumps all defendants together. *See Tatone v. SunTrust Mortg., Inc.*, 857 F. Supp. 2d 821, 831 (D. Minn. 2012) ("A complaint which lumps all defendants together and does not sufficiently allege who did what to whom, fails to

state a claim for relief because it does not provide fair notice of the grounds for the claims against a particular defendant.").

G. Plaintiff's Loss of Consortium, Wrongful Death, and Survivor Action Claims All Depend on Defendant's Liability for Steve Vallejo's Death and Should Be Dismissed With the Underlying Tort Claims.

As loss of consortium in Nebraska is a derivative claim, dependent on the defendant's liability for an underlying tort against the injured spouse, Count VI [12] for loss of consortium should be dismissed if the Court dismisses the other causes of action. *See Erickson v. U-Haul Int'l*, 767 N.W.2d 765, 774 (Neb. 2009) ("[A] loss of consortium claim derives from the harm suffered by the injured spouse. The rights of recovery by the uninjured spouse are based upon the injured spouse's right to recover for direct injuries. Not only must there be an injury to the injured spouse, but also there must be a compensable injury, that is, an injury for which the defendant is liable." (footnotes omitted)).

Similarly, wrongful death and survivor actions are predicated on the defendant's liability with respect to the deceased individual. *See* Nev. Rev. Stat. §§ 25-1401, 30-809(1). Therefore, Count V [13] also should be dismissed if the Court dismisses the other causes of action.

IV. CONCLUSION

For all of the foregoing reasons, Defendant respectfully requests that the Court enter an Order: (a) granting their Motion to Dismiss in its entirety; and (b) granting such other and further relief as is appropriate in the circumstances.

Dated this 23rd day of June, 2014.

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[12] Mislabeled in the Complaint as "Count VII."

[13] Mislabeled in the Complaint as "Count VI."

DEFENDANT AMGEN INC.

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CERTIFICATE OF SERVICE

I hereby certify that on June 23, 2014, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which sent notification of this filing to the following CM/ECF participant(s):

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/s/ Edward M. Fox
Edward M. Fox